

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Thursday 13th May 2004 7:15 for 7:45

Hopkinson Room,
University of Cambridge Computer Laboratory,
Pembroke Street, Cambridge

Statistical Considerations When Working for a CRO

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Statwood Partnership,
Hitchin

Abstract: Working for a CRO (Clinical Research Organisation) or pharmaceutical company, statisticians develop and evaluate the results of clinical trials to determine the safety and effectiveness of new medications. The main aspects of being a statistician are writing the analysis plan and producing accompanying tables, listings and figures. Issues in statistical analyses include the objective of the study, primary and secondary endpoints, multiplicity, bias in treatment comparisons, the patient population, multi-centre trials, assessing interactions, adjusting for covariates, handling missing data, statistical power and meeting regulatory guidelines. Occasionally further research is necessary and we have to base our analysis on previous studies. Programming, sometimes in collaboration with non-statisticians, is important in creating appropriate output. Clients include medics, clinicians and study investigators. Our job is to advise the client on the design and analysis of clinical trials to ensure the data can be analysed. Depending on the company you work for there are various processes in place to ensure that good quality information is passed to the client. Standard documents called SOPs (standard operating procedures) help to maintain certain standards ensuring working to FDA guidelines.

Speaker: After finishing her MSc at the University of Southampton, Melanie began work for Chiltern International, a small Clinical Research Organisation (CRO), based in Slough. She then moved back to Southampton to begin work at PPD Development, a much larger CRO. Melanie now works in Hitchin for the Statwood Partnership, another small CRO, where she has been for the past six months.

Directions: Enter the New Museums site through the arch from Pembroke Street. Turn to the left in front of the building with the brown iron staircase and pass through the passage way by the tree. Enter the lobby which is straight in front of you and find the back entrance to the Computing Service on your left. When inside follow the signs to the Hopkinson Room. It is not possible to park on the New Museums site in the evening. The back entrance to the Computing Service will be locked at 7:45. Arrivals after 7:45 can gain admittance by contacting the secretary on 07761769436. Arrivals after 7:45pm can gain admittance by contacting the secretary on 07761769436.

Provisional Next Meetings:

5th October – Steve Brooks (Statistical Laboratory). DATE TBC

24th November – Simon Godsill (Dept. of Engineering).

Supper: Some members eat regularly in the University Centre before each meeting at **6-15pm**. Feel free to join them.

Subscriptions: of 4 pounds are now due for the 2003-2004 session.

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